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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,022	07/14/2006	Yasuhiro Nakano	P29235	9439

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EXAMINER	
BASS, DIRK R	

ART UNIT	PAPER NUMBER
1777	

NOTIFICATION DATE	DELIVERY MODE
03/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,022	NAKANO ET AL.	
	Examiner	Art Unit	
	DIRK BASS	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 15-23* is/are pending in the application.

4a) Of the above claim(s) *7-9 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,10-12 and 15-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/16/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's request for continued examination filed November 16, 2010 is acknowledged. Claims 7-9 and 14 are withdrawn from consideration, claim 13 is cancelled, and claims 21-23 are newly added. Claims 1-6, 10-12, and 15-23 are further considered on the merits.

Response to Amendment

In response to the amendment, the examiner modifies the grounds of rejection set forth in the office action dated May 4, 2010.

Information Disclosure Statement

The information disclosure statement filed November 16, 2010 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language, specifically the Japanese office action with respect to application number 2005-512939. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. **Claims 1-6, 10-12, and 15-23** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 1, the pores of the supporting porous membrane have an average pore diameter half that of the porous membrane. When observing with a microscope, it is unclear how the larger pores of the porous membrane can be observed through the smaller pores of the supporting porous membrane. It is understood that the smaller pores of the supporting porous membrane would limit the focus to the size of said smaller pores, thereby making the larger pores of the porous membrane invisible to the viewer.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 1-6 and 17-23** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al., JP 2003-149096 (Tanaka, IDS) in view of Meyering et al., US 6280791 (Meyering).

3. Regarding claims 1-2 and 4-5, Tanaka discloses a porous membrane comprising an organic polymer and at least one supporting porous membrane (¶ 0019, 0030) wherein the porous membrane has an opening ratio between 10% and 90% (fig. 4), an average pore diameter of 7 to 14 μm (¶ 0019, 0030) with a standard deviation in pore diameter between 0 and 0.6 and percentage of through-pores to all the pores of the porous membrane is 30% or more (implicit in fig. 4).

4. Tanaka does not explicitly disclose the thickness of the porous membrane. However, Meyering discloses composite membranes for microfiltration techniques (abstract) wherein separate layers have a thickness of about 25 µm (C4/L4-17).

5. Therefore, at the time of invention, it would have been obvious to one having ordinary skill in the art to modify the membrane of Tanaka to comprise a membrane having thicknesses taught by Meyering since it has been shown that reducing the thickness of a membrane to less than 50 µm increases the overall flow rate and reduces the pressure drop across the membrane, thereby increasing performance of the filtration membrane (Meyering, C2/L57-59).

6. Furthermore, while Tanaka does not explicitly disclose the supporting porous membrane pore diameter, it can be envisaged that the pore diameter of the supporting porous membrane be at least 50% of the porous membrane, since Tanaka discloses multi-layered membranes comprising an upper membrane with pore diameters of 5.5-8.5 µm and a lower membrane with a pore diameter of 3.5 µm (¶ 0019).

7. Regarding claims 3 and 21-22, Tanaka (in view of Meyering) does not disclose that the average membrane thickness of the porous membrane is between .1 and 20 µm. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have such a membrane thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art (MPEP 2144.05, Section II, Part A). Additionally, Tanaka (in view of Meyering) discloses a

composite membrane wherein the supporting porous membrane has an average pore diameter between 1 and 100 µm (¶ 0019).

8. Regarding claim 6, Tanaka (in view of Meyering) discloses a composite porous membrane, where it is inherent that the porous membrane can be used to culture cell solutions, absent evidence to the contrary. As it has been held that a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987).*

9. Claim(s) 17-20 recite limitations regarding manipulative steps to bring about a specific product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (See MPEP 2113).

10. Regarding claim 23, Tanaka (in view of Meyering) discloses a porous membrane wherein the porous membrane has an opening ration between 15% and 80% (implicit in fig. 1-4).

11. **Claims 10-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka in view of Meyering as applied to claims 1-6, and in further view of Sheik-Ali, US 6645388 (Sheik-Ali).

12. As to Claims 10 and 12, Tanaka (in view of Meyering) discloses a leukocyte removal filter device comprising a plurality of filter elements (¶ 0019) and the composite membrane for use in the leukocyte depletion medium as shown in the 103(a) rejection of Claim 1.

13. Tanaka (in view of Meyering) does not appear to expressly disclose a prefilter (first filter) at the entrance of the suspension. However, Sheik-Ali discloses a prefilter in leukocyte depletion device at the entrance capable of removing leukocytes (C7/L27-30) prior to the other filtration elements at the exit side.

14. At the time of the invention it would have been obvious to a person having ordinary skill in the art to include the prefilter of Sheik-Ali in the leukocyte removal device of Tanaka (in view of Meyering). The motivation would have been to remove gel particulates from the hemocyte suspension to improve filtration efficiency.

15. Furthermore, It would have been obvious to a person having ordinary skill in the art that the composite membranes of Tanaka (in view of Meyering) have a higher effective filtration area (based an increased porosity and uniform pore size) and therefore requires a lesser volume of filter material to obtain the desired degree of leukocyte removal. It is desirable to have a lower filter volume as it reduces the amount of fluid retained in filter medium. Therefore, it would have been obvious to optimize the volume of the filter element to have a volume between 2 and 18 cm^3 as it has been held obvious to optimize a result effective variable. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

16. As to Claim 11, Sheik-Ali discloses that in order to achieve the desired leukocyte depletion it is necessary to have an effective area of the filter between 4 and 300 cm^2 (C7/L36-37).

17. **Claims 15-16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mussi et al., US 5665596 (Mussi) in view of Tanaka and Meyering as relied upon in the rejection of claim 1.

18. As to Claims 15-16, Mussi discloses a cell co-culture device (Fig. 1-4) which divides different cell groups and allows them to come into contact with each other (C4/L50-55); integrated cup-type culture container (12); tube having the cell culture diaphragm adhered to one end (14); and container which can hold the cup-type culture container and culture solution (Fig. 3).

19. Mussi does not appear to expressly disclose using the membrane of Tanaka in view of Meyering as shown in the rejection of Claim 6 above. However at the time of the invention it would have been obvious to a person having ordinary skill in the art to use the composite membrane of Tanaka in view of Meyering in the apparatus for cell co-culturing as it is well known that the honeycombed membrane structure is better for cultivating cells. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

20. Applicant's arguments filed November 16, 2010 have been fully considered but are moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1777

/DRB/
Dirk R. Bass